REMARKS

Claims 28, 30-32, 34, 39 and 41 remain pending in the present application. Claim 28 is amended to address formal matters; Claim 40 is canceled and the subject matter thereof inserted into claim 28. No new matter is added.

Rejections under 35 U.S.C. §112

Claims 28, 30-32, 34 and 39-41 stand rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The Examiner indicates that the claims are improperly directed to "a delivery vehicle consisting of tranilast", which was not envisioned.

Applicants redirect the Examiner's attention to claim 28 (reproduced in part below), wherein Applicants claim:

> A composition suitable for local, non-systemic administration of a drug to a body and directly to tissue within a body cavity having been subjected to a surgical procedure, said composition consisting of Tranilast or an analog thereof selected from the group consisting of..., a biodegradable polymer in a form selected from the group consisting of film, foam, fibers and filaments, suitable for local, non-systemic administration of said Tranilast or analog thereof, and optionally a therapeutic agent in an amount effective to provide the therapeutic effect intended by administration of said therapeutic agent. (Emphasis added).

In the above partial quotation, the Markush group components are excluded for clarity. Applicants respectfully request reconsideration of the rejection, since it is clear that the claim is adequately supported in the specification, as described in their prior response.

Claims 28, 30-32, 34 and 39-41 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicants traverse the basis for rejection and respectfully request reconsideration and withdrawal thereof, in view of the accompanying amendment to claim 28.

Rejection under 35 U.S.C. §102(b) over Mori et al.

Claims 28, 31, 32 and 39 stand rejected under 35 U.S.C. §102(b) as anticipated by Mori et al. (U.S. 6,239,177). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Mori et al. disclose external preparations containing Tranilast for high percutaneous absorption in the form of an aqueous base, containing (i) a solubilizer for Tranilast, (ii) a dispersant, (iii) an absorption aid, (iv) an adhesive and/or a shape retenting agent and (v) water (abstract).

The presently claimed composition is limited to having only Tranilast, a biodegradable polymer in the form of a film, foam, fibers and filaments and optionally a therapeutic agent. The delivery vehicle has (i) no solubilizer for Tranilast, (iv) no adhesive, and (v) no water to form an aqueous base, as required by Mori et al.

Mori et al. fail to disclose or suggest a delivery vehicle containing only Tranilast, a biodegradable polymer in the form of a film, foam, fibers or filaments and optionally a therapeutic agent.

Withdrawal of the rejection for lack of anticipation is requested.

Rejection under 35 U.S.C. 103(a) over Mori et al.

Claims 28, 30, and 34 are rejected under 35 U.S.C. 103(a) as obvious over Mori et al. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The deficiency of Mori et al. is discussed above and reiterated here. That is, Mori et al. fail to disclose or suggest compositions consisting of Tranilast or analogs thereof, a biodegradable polymer and optionally a therapeutic agent, as claimed herein.

One of skill in the art would not have been motivated to eliminate the solubilizer for Tranilast, dispersant, absorption aid, adhesive and/or a shape retenting agent and water from the Mori et al. compositions, so as to meet the limitations of the present claims.

Withdrawal of the rejection for failure to establish a *prima facie* case of obviousness is requested.

Rejection under 35 U.S.C. 103(a) over Mori et al.
in view of Pope et al.

Claims 28, 40 and 41 are rejected under 35 U.S.C. 103(a) as obvious over Mori et al. in view of Pope et al. (U.S. 5,948,822). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The deficiency of Mori et al. is discussed above and reiterated here. That is, Mori et al. fail to disclose or suggest compositions consisting of Tranilast or analogs thereof, a biodegradable polymer and optionally a therapeutic agent.

One of skill in the art would not have been motivated to eliminate the solubilizer for Tranilast, dispersant, absorption aid, adhesive and/or a shape retenting agent and water from the Mori et al. compositions, so as to meet the limitations of the present claims.

Pope et al. disclose topically administering a C_{18} to C_{26} aliphatic alcohol to a skin lesion in a pharmaceutically acceptable carrier (abstract) for treating or inhibiting the growth of hyperproliferative skin lesions, wherein the carrier may be white petrolatum, isopropyl myristate, lanolin or lanolin alcohols, mineral oil, sorbitan mono-oleate, propylene glycol, cetylstearyl alcohol, which can be combined with a detergent and mixed with water to form a lotion, gel, cream or semi-solid composition (col. 3, lines 41-49).

Pope et al. fail to cure the deficiency of Mori et al., since even if combined the cited reference teachings would fail to meet the present claim limitations.

Withdrawal of the rejection for failure to establish a *prima facie* case of obviousness is requested.

Rejections under 35 U.S.C. §103(a) over Isaji et al. in view of M'Timkulu et al.

Claims 28, 30, 31 and 32 stand rejected under 35 U.S.C. §103(a) as obvious over Isaji et al. (US 6,407,139) in view of M'Timkulu et al. (US 5,578,310). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Isaji et al. disclose compositions containing Tranilast in the form of powders, granules, fine granules, dry syrups, tablets, capsules, ointments, injections and eye drops, which can be formulated by admixing, diluting or dissolving with appropriate pharmaceutical additives such as excipients,

disintegrators, binders, lubricants, diluents, buffers, isotonicities, antiseptics, moistening agents, emulsifiers, dispersing agents, stabilizing agents and dissolving aids (col. 4, lines 30-41).

Applicants submit that Isaji et al. fail to disclose compositions consisting of Tranilast or its analogs, a biodegradable polymer in a form selected from the group consisting of film, foam, fibers, and filaments, and optionally a therapeutic agent.

M'Timkulu et al. disclose a topical bioadhesive ointment composition comprising an aqueous mineral oil emulsion which is readily spreadable and film-forming, and, upon application to moist skin or a mucosal surface, forms a stable, coherent layer thereon which resists removal therefrom by water or a body fluid associated with the mucosal surface to which the ointment composition is applied is disclosed. Also disclosed are pharmaceutical compositions containing the ointment compositions and a pharmaceutically active agent, e.g., TGFα; and methods of using and methods of preparing the compositions. (Abstract).

The Examiner cites M'Timkulu et al. for the proposition that spreading an ointment results in a film, and since Isaji et al. disclose that their formulation can be prepared in the form of ointments, that the Isaji et al. ointments, when spread topically, result in a film within the scope of the present invention. At page 8 of the Office Action, the Examiner concludes:

> Claim 31 and 32 are directed to the properties/characteristic of the device so that the composition of Isaji meets these claims. When polymers are lactides, claim 30 is met as the barrier and also meeting the barrier of claim 28. Isaji does not teach the forms of the product, namely, foam or film or fiber or filament. However, when an ointment is topical applied it is generally spread into film according to claims 1 and 16 of US 5,578,310.

> Therefore, taking the teaching of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that topically applying the ointment of Isaji would expected form a film as contemplated for topical delivery of tranilast. (Emphasis added).

While it is true that Isaji et al. disclose ointment as a vehicle for Tranilast, patentees fail to provide any guidance whatsoever as to the formulation of such an ointment. As such, it is impossible to determine whether an ointment formulated according to Isaji et al. would include a biodegradable polymer, as per the present claims. Thus, according to the rejection, one skilled in the art would need to look to the secondary reference, M'Timkulu et al., for guidance.

M'Timkulu et al. disclose formulation of their ointments at column 2, lines 35-50, to wit:

> A topical bioadhesive ointment composition of this invention is a viscous aqueous mineral oil emulsion which comprises water; mineral oil; a water-dispersible particulate hydrophilic hydroxypropyl methylcellulose suspended in the aqueous phase of the emulsion in an amount effective to form, when the emulsion is spread on a moist skin or mucosal surface, a stable, coherent film which resists removal therefrom by water or a body fluid associated therewith; a water-soluble polyalkylene glycol dissolved in the aqueous phase of the emulsion in an amount sufficient to reduce the water activity of the emulsion in order to retain the hydroxypropyl methylcellulose therein in particulate, non-fully hydrated form and to increase the viscosity thereof to a spreadable viscous paste; and, optionally, a non-ionic surfactant in an amount sufficient to render the emulsion stable for storage.

The ointment preparations disclosed by M'Timkulu et al. contain a number of components outside the scope of the present claims: water; mineral oil; hydroxypropyl methylcellulose and polyalkylene glycol. Thus, if the skilled artisan were to combine the cited references, and form an ointment according to the Examiner's suggestion, such ointment would be outside the scope of the present claims, despite containing Tranilast.

Withdrawal of the rejection is requested.

Rejection under 35 U.S.C. 103(a) over Isaji et al. in view of M'Timkulu et al. and further in view of Akhtar et al.

Claims 28, 40 and 41 are rejected under 35 U.S.C. 103(a) as obvious over Isaji et al. in view of M'Timkulu et al. and further in view of Akhtar et al. (U.S. 5,432,163). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The deficiencies of the combination of Isaji et al. and M'Timkulu et al. are discussed above and reiterated herein.

Akhtar et al. disclose anti-proliferative and anti-inflammatory compounds which are derivatives of pentose monosaccharides (title). The Akhtar et al. compounds are disclosed to administered orally, topically, rectally, anterally, internally, by boluses, or parenterally, preferably orally, in forms such as granules, powders, coated tablets, microcapsules, suppositories, syrups, elixirs, suspensions, emulsions, drops or injectable solutions (col. 8, lines 40-47).

Akhtar et al. fail to disclose or suggest incorporating their new compounds in compositions consisting of Tranilast or its analogs and a biodegradable polymer in a form selected from the group consisting of film, foam, fibers, and filaments and therefore cannot cure the deficiency of Isaji et al. in view of M'Timkulu et al., as applied to the present claims.

Further, even if the skilled artisan were to have been motivated to so combine the reference teachings, the resulting composition would include a number of components (disclosed by M'Timkulu et al.) which fall outside the scope of the present claims.

Withdrawal of the rejection for failure to establish a *prima facie* case of obviousness is requested.

Rejection for provisional nonstatutory double patenting over copending application no. 10/780,452 in view of Chandrasekar et al. Or Miyazawa et al.

Claims 28, 30-32 and 39-41 are provisionally rejected for nonstatutory double patenting over claims 14-19, 21-24 and 27-41 of copending application no. 10/780,452, in view of Chandrasekar et al. ("Platelets and Restenosis") or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat"). Reconsideration of the double patenting rejection is requested in view of the accompanying amendment herein.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(14788).

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully solicited.

If the Examiner has any questions or wishes to discuss this application,

the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

/Michael J. Mlotkowski/

Michael J. Mlotkowski
Reg. No. 33,020
Attorney for Applicants
703-584-3270

DATED: September 22, 2009

CORRESPONDENCE ADDRESS:

Roberts Mlotkowski Safran & Cole
P.O. Box 10064
McLean, VA 22102-8064